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Dated: November 8, 2007 Signature: Isaac Medrano
Isaac Medrano

1AP16 Rec'd PCT/PTO 08 NOV 2007

PTO-1390 (Rev. 07-2005)

Approved for use through 03/31/2007. OMB 0651-0021
U. S. Patent and Trademark Office; U. S. DEPARTMENT OF COMMERCE

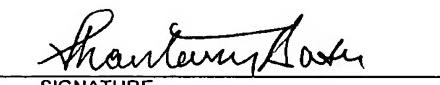
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371		ATTORNEY'S DOCKET NUMBER 560252000700
INTERNATIONAL APPLICATION NO. PCT/US2005/001225	INTERNATIONAL FILING DATE 13 January 2005	U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/586,209
PRIORITY DATE CLAIMED 13 January 2004		
TITLE OF INVENTION CONTROLLED RELEASE CGRP DELIVERY COMPOSITION FOR CARDIOVASCULAR AND RENAL INDICATIONS		
APPLICANT(S) FOR DO/EO/US Jeffrey L. SOUTHARD et al.		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
<p>1. <input type="checkbox"/> This is a FIRST submission of items concerning a submission under 35 U.S.C. 371.</p> <p>2. <input checked="" type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371.</p> <p>3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.</p> <p>4. <input type="checkbox"/> The US has been elected (Article 31).</p> <p>5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371 (c)(2)) a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> has been communicated by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</p> <p>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)) a. <input type="checkbox"/> is attached hereto. b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</p> <p>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> have been communicated by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input type="checkbox"/> have not been made and will not be made.</p> <p>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</p> <p>9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). (1 page)</p> <p>10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</p>		
Items 11 to 20 below concern document(s) or information included:		
<p>11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</p> <p>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</p> <p>13. <input type="checkbox"/> A preliminary amendment.</p> <p>14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.</p> <p>15. <input type="checkbox"/> A substitute specification.</p> <p>16. <input checked="" type="checkbox"/> A power of attorney and/or change of address letter. (1 page)</p> <p>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 – 1.825.</p> <p>18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4).</p> <p>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</p>		

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U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/586,209	INTERNATIONAL APPLICATION NO. PCT/US2005/001225	ATTORNEY'S DOCKET NUMBER 560252000700																					
20. <input checked="" type="checkbox"/> Other items or information: <ul style="list-style-type: none"> > Copy of Notification of Missing Requirements (2 pages) > Petition for Extension of Time (1 page) > Statement Under 37 CFR 3.73(b) + copy of Assignment (2 pages) > Return Receipt Postcard 																							
The following fees have been submitted <table border="1" style="width: 100%;"> <tr> <td style="width: 60%;">21. <input type="checkbox"/> Basic national fee (37 CFR 1.492(a))</td> <td style="width: 20%; text-align: right;">\$300</td> <td style="width: 20%; text-align: center;">CALCULATIONS</td> </tr> <tr> <td><input type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)</td> <td style="text-align: right;">\$0</td> <td style="text-align: center;">PTO USEONLY</td> </tr> <tr> <td>All other situations</td> <td style="text-align: right;">\$200</td> <td></td> </tr> <tr> <td>23. <input type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)</td> <td style="text-align: right;">\$0</td> <td></td> </tr> <tr> <td>Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority.....</td> <td style="text-align: right;">\$100</td> <td></td> </tr> <tr> <td>International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB.....</td> <td style="text-align: right;">\$400</td> <td></td> </tr> <tr> <td>All other situations.....</td> <td style="text-align: right;">\$500</td> <td></td> </tr> </table>			21. <input type="checkbox"/> Basic national fee (37 CFR 1.492(a))	\$300	CALCULATIONS	<input type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)	\$0	PTO USEONLY	All other situations	\$200		23. <input type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)	\$0		Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority.....	\$100		International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB.....	\$400		All other situations.....	\$500	
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All other situations.....	\$500																						
TOTAL OF 21, 22 and 23 =																							
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.																							
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)																					
- 100 =	/50 =	x \$250.00																					
Surcharge of \$130 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).																							
<table border="1" style="width: 100%;"> <tr> <th>CLAIMS</th> <th>NUMBER FILED</th> <th>NUMBER EXTRA</th> <th>RATE</th> </tr> <tr> <td>Total claims</td> <td>47 - 47 =</td> <td>0</td> <td>x 50.00</td> </tr> <tr> <td>Independent claims</td> <td>6 - 6 =</td> <td>0</td> <td>x 200.00</td> </tr> <tr> <td colspan="3">MULTIPLE DEPENDENT CLAIM(S) (if applicable)</td> <td>+</td> </tr> </table>			CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	Total claims	47 - 47 =	0	x 50.00	Independent claims	6 - 6 =	0	x 200.00	MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+					
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE																				
Total claims	47 - 47 =	0	x 50.00																				
Independent claims	6 - 6 =	0	x 200.00																				
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+																				
Petition for Extension of Time Under 37 CFR 1.136(a)																							
TOTAL OF ABOVE CALCULATIONS = \$ 2,360.00																							
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½.																							
SUBTOTAL = \$ 1,180.00																							
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).																							
TOTAL NATIONAL FEE = \$ 1,180.00																							
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +																							
\$																							
11/14/2007 LLANDGRA 00000035 031952 10586209		TOTAL FEES ENCLOSED = \$ 1,180.00																					
65.00 DA		Amount to be refunded: \$																					
		Amount to be charged \$																					

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U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/586,209	INTERNATIONAL APPLICATION NO. PCT/US2005/001225	ATTORNEY'S DOCKET NUMBER 560252000700
<p>a. <input type="checkbox"/> A check in the amount of \$ _____ to cover the above fees is enclosed.</p> <p>b. <input checked="" type="checkbox"/> Please charge my Deposit Account No. 03-1952 in the amount of \$ 1,180.00 to cover the above fees. A duplicate copy of this sheet is enclosed.</p> <p>c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 03-1952. A duplicate copy of this sheet is enclosed.</p> <p>d. <input type="checkbox"/> Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038</p>		
<p>NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.</p>		
SEND ALL CORRESPONDENCE TO:  SIGNATURE		
<hr/> NAME Shantanu Basu <hr/>		
CUSTOMER NUMBER: 25226 <hr/> REGISTRATION NUMBER 43,318 <hr/>		



UNITED STATES PATENT AND TRADEMARK OFFICE

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U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/586,209	Jeffrey L. Southard	560252000700

25226
MORRISON & FOERSTER LLP
755 PAGE MILL RD
PALO ALTO, CA 94304-1018

RECEIVED

APR 12 2007

Morrison & Foerster LLP
Palo Alto

INTERNATIONAL APPLICATION NO.	
PCT/US05/01225	

I.A. FILING DATE	PRIORITY DATE
01/13/2005	01/13/2004

CONFIRMATION NO. 2819
371 FORMALITIES LETTER



OC000000023272349

Date Mailed: 04/09/2007

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Indication of Small Entity Status
- Copy of the International Application filed on 07/13/2006
- Copy of the International Search Report filed on 07/13/2006
- Small Entity Statement filed on 07/13/2006
- U.S. Basic National Fees filed on 07/13/2006
- Priority Documents filed on 07/13/2006

Georgina
DOCKETED miss Reg. Resp. Due
LPS

DUE DATE: 6 - 9 - 2007

FINAL DUE DATE: 11 - 9 - 2007

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of \$65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

Total additional fees required for this application is **\$65** for a Small Entity:

- **\$65** Surcharge.

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.
<https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html>

For more information about EFS-Web please call the USPTO Electronic Business Center at 1-866-217-9197 or visit our website at <http://www.uspto.gov/ebc>.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

CHRISTINE S WASHINGTON

Telephone: (703) 308-9140 EXT 228

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/586,209	PCT/US05/01225	560252000700

FORM PCT/DO/EO/905 (371 Formalities Notice)